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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,716	02/16/2006	Masato Kato	18655	8342

23389 7590 08/19/2008
SCULLY SCOTT MURPHY & PRESSER, PC
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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
08/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,716	KATO ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of the species of antibody-dependent cell mediated cytotoxicity in the reply filed 6/5/08 is acknowledged.

However, upon reconsideration, the restriction requirement mailed 3/17/08 is withdrawn.

Claims 1-20 are under examination.

2. The drawings are objected to because the Y axis label for figure 10c is missing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. Claim 15 is objected to because of the following informalities: The claim recites "the said" inappropriate immuno-activity, which is grammatically incorrect. Appropriate correction is required.

4. Claim 19 is objected to because of the following informalities: The claim recites "allergenic" bone-marrow graft. Is assumed that this is a typographical error, and the claim is intended to recite "allogenic" bone-marrow, as recited in claim 13. Appropriate correction is required.

5. It is noted that claim 13 does not depend from a preceding claim, but rather depends from claim 17. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another

preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 10, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 7 recites the limitation "the APC and/or lymphocyte" in line 2. There is insufficient antecedent basis for this limitation in the claim, or in claims 1 and 2, from which it depends.

B) Claim 10 recites the limitation "said subject" in line 2. There is insufficient antecedent basis for this limitation in the claim.

C) Claim 14 recites the limitation "the lymphocyte" in line 1. There is insufficient antecedent basis for this limitation in the claim, or in claim 12, from which it depends.

8. Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

The claims are incomplete for omitting essential steps. While all of the technical details need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The instant claims are drawn to a method for the therapeutic treatment of a condition characterized by the aberrant, unwanted, or otherwise inappropriate immuno-activity of graft. However, the only recited method step involves contacting the graft with an antibody that binds to CD83. This might encompass contacting a graft in vitro with an antibody, and in the absence

of additional method steps it is not clear how the method could result in the therapeutic treatment of a condition. For example, the claims do not recite that the graft is contacted with the antibody in a subject (i.e. that the antibody is administered to a subject), nor do they recite that an antibody contacted graft is administered to a subject.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 2, 5, and 12-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of "functional equivalents", "derivatives', "homologs", "analogs", "chemical equivalents", or "mimetics" of an antibody which binds to CD83.

The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus

The instant claims are drawn to methods employing a genus of "functional equivalents", "derivatives', "homologs", "analogs", "chemical equivalents", or "mimetics" of an antibody which binds to CD83. The specification on page 15 discloses that functional and chemical equivalents should be understood as molecules exhibiting any one or more of the functional activities of the agent (i.e. the anti-CD83 antibodies), that

may be derived from any source. Particular functional equivalents of the instant claims include derivatives homologs, analogs, etc. Thus, the functional equivalents, analogs, derivatives, homologs, etc. encompass any molecule that binds to CD83. Thus, the claims might encompass structurally different molecules including protein ligands, peptides, or even small molecules. The specification does not provide any correlation between the structure of the members of the claimed genus and the function of binding to CD83. Furthermore, there is no art recognized correlation between said structure and function. Additionally, the only "functional equivalents", "derivatives', "homologs", "analogs", "chemical equivalents", or "mimetics" disclosed by the specification are anti-CD83 antibodies or antigen binding fragments thereof. This is not representative of the structurally different "functional equivalents", "derivatives', "homologs", "analogs", "chemical equivalents", or "mimetics" encompassed by the claims. Thus, one of skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

11. Claims 1-9 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method of downregulating the immuno-activity of a myeloid dendritic cell, a T cell, or an immuno-competent graft comprising inducing cell lysis with an antibody or antigen-binding fragment thereof that binds to CD83, wherein the method inhibits or down-regulates the functional activities of a cell, a method for downregulating an immune response in a subject comprising inducing lysis of a dendritic cell and/or T cell, a method of treatment of a condition characterized by the aberrant, unwanted, or otherwise inappropriate immuno-activity of an immuno-competent graft with an antibody or antigen binding fragment thereof that binds to CD83, wherein the method inhibits or downregulates the immuno-activity of dendritic cells and/or T cells, or the graft;

does not reasonably provide enablement for a method of modulating the immuno-activity of a myeloid dendritic cell or a T cell comprising inducing cell lysis, or a method of down-regulating the immuno-activity of an immuno-competent graft, wherein the methods prevent the functional activities of a cell, methods of modulating the immuno-activity of a cell with a functional equivalent, derivative, homolog, analog, chemical

equivalent, or mimetic of a CD83 binding antibody, a method for modulating an immune response in a subject comprising inducing lysis of a dendritic cell and/or T cell, a method of treatment of a condition characterized by the aberrant, unwanted, or otherwise inappropriate immuno-activity of an immuno-competent graft with a functional equivalent, derivative, homolog, analog, chemical equivalent, or mimetic of an CD83 binding antibody, a method of treatment of a condition characterized by the aberrant, unwanted, or otherwise inappropriate immuno-activity of an immuno-competent graft with an antibody or antigen binding fragment thereof that binds to CD83, wherein the method prevents the immuno-activity of dendritic cells, T cells, or the graft, and a method of treatment of a condition characterized by an aberrant, unwanted, or otherwise inappropriate immune response in a subject with a CD83 antibody.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, *in re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

"The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (MPEP 2164.03)" The MPEP further states that physiological activity can be considered inherently unpredictable.

The specification provides insufficient guidance to enable

claims drawn to the method as broadly claimed. Claims 1-9 are drawn to a method of modulating the immuno-activity of a cell, or a method of modulating an immune response comprising inducing cell lysis of a dendritic cell and/or T cell after contact with an antibody that binds to a surface activation marker of said cells, such as CD83. The term "modulates" encompasses both an increase and a decrease in the immuno-activity of the cell or the immune response. While causing lysis of dendritic cells and T cells might be expected to result in a decrease in immune activity of said cells, or to result in a decreased or suppressed immune response, it is not clear how the immuno-activity or immune response could be increased, as is encompassed by the instant claims.

Additionally, claims 2, 5, and 12-19 encompass modulating the immuno-activity of a cell, downregulating the immuno-activity of a graft, or treating a condition employing an anti-CD83 antibody, or a functional equivalent, derivative, homolog, analog, chemical equivalent, or mimetic thereof. The specification on page 15 discloses that functional and chemical equivalents should be understood as molecules exhibiting any one or more of the functional activities of the agent (i.e. the anti-CD83 antibodies), that may be derived from any source. Particular functional equivalents of the instant claims include derivatives homologs, analogs, etc. Thus, the functional equivalents, analogs, derivatives, homologs, etc. encompass any molecule that binds to CD83. Thus, the claims might encompass methods employing the natural ligand of CD83 as the "functional equivalent" that binds to CD83. However, the state of the art is such that the functional properties and the putative ligands of CD83 have yet to be defined (See Klein et al., 2005, page 485 in particular). The instant specification does not provide any guidance as to how to identify "functional equivalents" of anti-CD83 antibodies, such as the natural ligand of CD83. The only "functional equivalents" disclosed by the instant specification are antigen binding antibody fragments. However, given the level of unpredictability in the art (i.e. the unknown structure of other CD83 ligands), it would require undue experimentation to make other CD83 binding “equivalents”, as is encompassed by the instant claims.

Additionally, claim 20 is drawn to a method of treating a condition characterized by an aberrant, unwanted, or otherwise inappropriate immune response in a subject. This might encompass treating a wide range of conditions. For example, the

instant claims might encompass treating conditions such as B malignancies or viral infections resulting in immune suppression (i.e. an "aberrant" or "unwanted" immune response). It is unclear how T cell or dendritic cell depletion would be useful for treating conditions such as B cell malignancy or viral infection, the goal of which is to boost the immune response (see Gowans et al., 2004 and Franki et al., 2008). Thus, based on the unpredictability of the art, the instant specification must provide a sufficient disclosure to enable one of skill in the art to treat conditions characterized by aberrant, unwanted, or otherwise inappropriate immune responses, as broadly claimed. The instant specification does not provide any experimental data demonstrating the therapeutic effectiveness of anti-CD83 antibody treatment, but provides in vitro data demonstrating that anti-CD83 inhibits a mixed lymphocyte reaction. While therapies targeted at dendritic cells and T cells have been demonstrated to be effective in treating transplantation rejection and graft-versus host disease (see Klansinsirkul et al.), the state of the art is such that applying said therapies to the broad range of conditions encompassed by the instant claim is highly unpredictable. Thus, it would require undue experimentation to practice the invention as broadly claimed.

Additionally, claims 1-8 and 11-20 encompass preventing the immuno-activity of a dendritic cell, T cell, or a graft employing a CD83 antibody that induces cell lysis. This encompasses completely preventing any functional activity of dendritic cells or T cells, or a graft in vivo by administering an antibody. While it may be possible to downregulate or inhibit the activities of said cells by inducing cell lysis, a complete prevention would require lysing every cell, which would be unlikely after antibody administration. The examples in the instant specification demonstrate that a CD83 antibody inhibits (but does not prevent) a mixed lymphocyte reaction in vitro. Thus, based on the unpredictability of the art and the lack of guidance by the instant specification, it would require undue experimentation to practice the invention as broadly claimed.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12, 14-18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated U.S. Patent 5,316,920, as evidenced by U.S. Patent 5,766,570.

The ‘920 patent teaches that HB15 is a molecule expressed by dendritic cells and langerhan's cells, as well as activated T cells (see column 5 and 10, in particular). As evidenced by the ‘570 patent, HB15 is another name for CD83 (see column 2 in particular). The '920 patent also teaches the therapeutic use of antibodies which bind to HB15 to inhibit the immune response (see columns 2-3 in particular). The '920 patent also teaches that the antibodies can be used therapeutically to deliver toxins to HB15 expressing cells (i.e. administering antibodies conjugated to a toxic component, or antigen binding “derivatives”, see column 3 in particular). The method of the '920 patent would inherently result in the contact of dendritic cells/T cells with the antibody in vivo, and would also inherently result in the lysis of said cells, since it is the same as the antibody of the instant claims. The '920 patent also teaches monoclonal antibodies reactive with HB15 proteins (see column 3 in particular). The ‘920 patent also teaches that antibodies to HB15 can be used as therapeutic agents to treat human organ transplants (see column 2 and 13 in particular). The administration of antibodies for the therapeutic treatment of organ transplantation would inherently result in the downregulation of the immunoactivity of a graft (including graft versus host disease), and lysis of DC, and/or T cells, since it is the same as the method of the instant claims.

Thus, the reference clearly anticipates the invention.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered

therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,316,920, in view of Klansinsirkul et al., April 2002, as evidenced by U.S. Patent 5,766,570

The teachings of the '920 patent, and the evidentiary teachings of the '570 patent are described above.

The '920 patent does not teach treating allogenic bone marrow transplantation.

Klansinsirkul et al. teach that antibodies that bind to T cells and dendritic cells are useful for administration to patients to inhibit rejection and suppress graft versus host disease following unrelated donor bone marrow transplantation via their ability to eliminate said cells via antibody-dependent cell cytotoxicity (see page 2586 in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the therapeutic method of treating organ transplantation with anti-HB15 antibodies of the '920 patent, to treat bone marrow transplantation as the type of organ transplant, as taught by Klansinsirkul et al. The ordinary artisan would have been motivated to do so, and have a reasonable expectation of success, since the '920 patent teaches that HB15 antibodies, which bind T cells and dendritic cells, are useful as a therapeutic agent to treat organ transplantation, and Klansinsirkul et al. teach that antibodies that bind to T cells and dendritic cells are effective in inhibiting rejection and suppressing graft versus host disease following unrelated bone marrow transplantation.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 11-13, 15-16, 18-23 of copending Application No. 10/523,756, in view of U.S. Patent 5,316,920. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '756 application claims a method of modulating the immuno-activity of an APC, and a method of modulating an immune response in a subject employing an agent that binds to an activation molecule of an APC. The '756 application further claims that the APC is a dendritic cell, and the agent is an antibody. The '756 application also claims that the antibody is a monoclonal antibody, that the antibody is conjugated to a toxic component, and that the antibody induces lysis of the APC. It would have been obvious to use a CD83 antibody as the agent that binds to a dendritic cell marker, since the '920 patent teaches CD83 (HB15) is a marker of dendritic cells, and that antibodies specific for CD83 (HB15) can be used to inhibit the immune response (see columns 2-3 in particular).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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